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PUBLIC HEALTH SERVICE
BIOLOGICAL MATERIALS LICENSE AGREEMENT

This **Agreement** is entered into between the National Institutes of Health ("**NIH**") or the Food and Drug Administration ("**FDA**"), hereinafter singly or collectively referred to as "**PHS**", agencies of the United States Public Health Service within the Department of Health and Human Services ("**HHS**") through the Office of Technology Transfer, **NIH**, having an address at 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804, U.S.A. and _____ ("**Licensee**"), a corporation of _____, having an office at _____.

1. Definitions:

   (a) "**Materials**" means the following biological materials including all progeny, subclones, and unmodified derivatives thereof:
   _____, as described in
   _____
   _____ and developed in the laboratory of
   _____.

   (b) "**Licensed Products**" means _____.

   (c) "**Net Sales**" means the total gross receipts by **Licensee** for sales of **Licensed Products** or from income from leasing, renting, or otherwise making **Licensed Products** available to others without sale or other dispositions transferring title, whether invoiced or not, less returns and allowances, packing costs, insurance costs, freight out, taxes or excise duties imposed on the transaction (if separately invoiced), and wholesaler and cash discounts in amounts customary in the trade to the extent actually granted. No deductions shall be made for commissions paid to individuals, whether they are with independent sales agencies or regularly employed by **Licensee**, or for the cost of collections.

   (d) **"Licensed Field of Use**" means _____.

2. **Licensee** desires to obtain a license from **PHS** to use the **Materials** provided under this **Agreement** in its commercial research or product development and marketing activities. **Licensee** represents that it has the facilities, personnel, and expertise to use the **Materials** or the **Licensed Products** for commercial purposes and agrees to expend reasonable efforts and resources to develop the **Materials** or the **Licensed Products** for commercial use or commercial research.

3. **PHS** hereby grants to **Licensee**:

   (a) a worldwide, non-exclusive license to make, have made, and use the **Materials** or the **Licensed Products**; and

   (b) a worldwide, non-exclusive license to sell and have sold, to offer to sell and to import the **Licensed Products** in the **Field(s) of Use**.

4. In consideration of the grant in Paragraph 3, **Licensee** hereby agrees to make the following payments to **PHS**:

   (a) Within thirty (30) days of its execution of this **Agreement**, a noncreditable, nonrefundable license issue royalty of _____ dollars ($X).

   (b) A nonrefundable minimum annual royalty of _____ dollars ($X) which shall be due and payable on January 1 of each calendar year and may be credited against earned royalties for sales made in that year. The minimum annual royalty for the first calendar year of this **Agreement** is due and payable within thirty (30) days from the effective date of this **Agreement** and may be prorated according to the fraction of the calendar year remaining between the effective date of this **Agreement** and the next subsequent January 1.

   (c) An earned royalty of _____ percent (X%) of **Net Sales**, which shall be due and payable within sixty (60) days of the end of each calendar year.

   (d) All payments required under this **Agreement** shall be paid in U.S. dollars and payment options are listed in Appendix C. For conversion of foreign currency to U.S. dollars, the conversion rate shall be the New York foreign exchange rate quoted in *The Wall Street Journal* on the day that the payment is due.

      i) Any loss of exchange, value, taxes, or other expenses incurred in the transfer or conversion to U.S. dollars shall be paid entirely by **Licensee**; and

      ii) Additional royalties may be assessed by **PHS** on any payment that is more than ninety (90) days overdue at the rate of one percent (1%) per month. This one percent (1%) per month rate may be applied retroactively from the original due date until the date of receipt by **PHS** of the overdue payment and additional royalties. The payment of any additional royalties shall not prevent **PHS** from exercising any other rights it may have as a consequence of the lateness of any payment.

5. Upon receipt by **PHS** of the license issue royalty and the prorated first year minimum annual royalty and verification of these royalties, **PHS** agrees to provide **Licensee** with samples of the **Materials**, as available, and to replace these **Materials**, as available, at reasonable cost, in the event of their unintentional destruction. **PHS** shall provide the **Materials** to **Licensee** as specified in Appendix A.

6. **Licensee** agrees to make written reports to **PHS** within sixty (60) days of December 31 for each calendar year. This report shall state: the number, description, and aggregate **Net Sales** of **Licensed Products** made, sold, or otherwise disposed of; the total gross income received by **Licensee** from leasing, renting, or otherwise making **Licensed Products** available to others without sale or other disposition transferring title, during the calendar year; and the resulting calculation of earned royalties due **PHS** pursuant to Paragraph 4(c) and as shown in the example in Appendix B. **Licensee** shall submit each report to **PHS** at the Mailing Address for **Agreement** notices indicated on the Signature Page.

7. **Licensee** agrees to supply the laboratory of Dr. _____, at **PHS**, at no charge, reasonable quantities of **Materials** or the **Licensed Products** that **Licensee** makes, uses, sells, or offers for sale or otherwise makes available for public use. **Licensee** also agrees to supply, to the Mailing Address for **Agreement** notices indicated on the Signature Page, the Office of Technology Transfer, **NIH** with insert samples of the **Licensed Products** or their packaging for educational and display purposes only.

8. This **Agreement** shall become effective on the date when the last party to sign has executed this **Agreement**, unless the provisions of Paragraph 25 are not fulfilled, and shall expire _____ (X) years from this effective date, unless previously terminated under the terms of Paragraphs 16 or 17.

9. As part of **Licensee's** performance under this **Agreement**, **Licensee** agrees to make the **Licensed Products** available to the public within _____ (X) months.

10. **Licensee** agrees to retain control over the **Materials** and the **Licensed Products**, and not to distribute them to third parties without the prior written consent of **PHS** except as provided in Paragraph 3.

11. This **Agreement** does not preclude **PHS** from distributing the **Materials** or the **Licensed Products** to third parties for research or commercial purposes.

12. By this **Agreement**, **PHS** grants no patent rights expressly or by implication to any anticipated or pending **PHS** patent applications or issued patents.

13. NO WARRANTIES, EXPRESS OR IMPLIED, ARE OFFERED AS TO THE MERCHANTABILITY OR FITNESS FOR ANY PURPOSE OF THE **MATERIALS** PROVIDED TO **LICENSEE** UNDER THIS **AGREEMENT**, OR THAT THE **MATERIALS** OR THE **LICENSED PRODUCTS** MAY BE EXPLOITED WITHOUT INFRINGING THE PATENT RIGHTS OF ANY THIRD PARTIES. **Licensee** accepts license rights to the **Materials** and the **Licensed Products** "as is", and **PHS** does not offer any guarantee of any kind.

14. **Licensee** agrees to indemnify and hold harmless the United States Government from any claims, costs, damages, or losses that may arise from or through **Licensee's** use of the **Materials** or the **Licensed Products**. **Licensee** further agrees that it shall not by its action bring the United States Government into any lawsuit involving the **Materials** or the **Licensed Products**.

15. **Licensee** agrees in its use of the **Materials** or the **Licensed Products** to comply with all applicable statutes, regulations, and guidelines, including **PHS** and **HHS** regulations and guidelines. **Licensee** agrees not to use the **Materials** or the **Licensed Products** for research involving human subjects or clinical trials in the United States without complying with 21 CFR Part 50 and 45 CFR Part 46. **Licensee** agrees not to use the **Materials** or the **Licensed Products** for research involving human subjects or clinical trials outside of the United States without notifying **PHS**, in writing, of such research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to **PHS** of research involving human subjects or clinical trials outside of the United States shall be given no later than sixty (60) days prior to commencement of such research or trials.

16. **Licensee** may terminate this **Agreement** upon sixty (60) days written notice to **PHS**.

17. **PHS** may terminate this **Agreement** if **Licensee** is in default in the performance of any material obligation under this **Agreement**, and if the default has not been remedied within ninety (90) days after the date of written notice by **PHS** of the default.

18. Upon termination or expiration of this **Agreement**, **Licensee** agrees to return all **Materials** and the **Licensed Products** to **PHS**, or provide **PHS** with written certification of their destruction.

19. Within ninety (90) days of termination or expiration of this **Agreement**, **Licensee** agrees to submit a final report to **PHS**, and to submit to **PHS** payment of any royalties due.

20. **Licensee** is encouraged to publish the results of its research projects using the **Materials** or the **Licensed Products**. In all oral presentations or written publications concerning the **Materials** or the **Licensed Products**, **Licensee** shall acknowledge the contribution of Dr. _____ and the **PHS** agency supplying the **Materials**, unless requested otherwise by **PHS** or Dr. _____.

21. This **Agreement** shall be construed in accordance with U.S. Federal law, as interpreted and applied by the U.S. Federal courts in the District of Columbia. Federal law and regulations shall preempt any conflicting or inconsistent provisions in this **Agreement**. **Licensee** agrees to be subject to the jurisdiction of U.S. courts.

22. This **Agreement** constitutes the entire understanding of **PHS** and **Licensee** and supersedes all prior agreements and understandings with respect to the **Materials** or the **Licensed Products**.

23. The provisions of this **Agreement** are severable, and in the event that any provision of the **Agreement** shall be determined to be invalid or unenforceable under any controlling body of law, the invalidity or unenforceability of any provision of this **Agreement**, shall not in any way affect the validity or enforceability of the remaining provisions of this **Agreement**.

24. Paragraphs 13, 14, and 20 of this **Agreement** shall survive termination or expiration of this **Agreement**.

25. The terms and conditions of this **Agreement** shall, at **PHS'** sole option, be considered by **PHS** to be withdrawn from **Licensee's** consideration and the terms and conditions of this **Agreement**, and the **Agreement** itself to be null and void, unless this **Agreement** is executed by the **Licensee** and a fully executed original is received by **PHS** within sixty (60) days from the date of **PHS** signature found at the Signature Page.

SIGNATURES BEGIN ON NEXT PAGE

PHS BIOLOGICAL MATERIALS LICENSE AGREEMENT

SIGNATURE PAGE

In Witness Whereof, the parties have executed this **Agreement** on the dates set forth below. Any communication or notice to be given shall be forwarded to the respective addresses listed below.

For **PHS**:

_____ _____

Steven M. Ferguson Date
Director, Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health

Mailing Address for **Agreement** notices:

Chief, Monitoring & Enforcement Branch, DTDT
Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852-3804 U.S.A.

For **Licensee** (Upon, information and belief, the undersigned expressly certifies or affirms that the contents of any statements of **Licensee** made or referred to in this document are truthful and accurate.):
by:

_____ _____

Signature of Authorized Official Date

_____

Printed Name

_____

Title

I. Official and Mailing Address for **Agreement** notices:

_____

_____

_____

II. Official and Mailing Address for Financial notices (**Licensee's** contact person for royalty payments)

_____
Name

_____
Title

Mailing Address:

_____

_____

_____

_____

Email Address: _____

Phone: _____

Fax: _____

Any false or misleading statements made, presented, or submitted to the **Government**, including any relevant omissions, under this **Agreement** and during the course of negotiation of this **Agreement** are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§3801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) and/or imprisonment).

APPENDIX A – SHIPPING INFORMATION

Licensee's Shipping Contact: information or questions regarding shipping should be directed to Licensee's Shipping Contact at:

_____ _____

Shipping Contact's Name Title

Phone: () _____ Fax: () _____ E-mail: _____

Shipping Address: Name & Address to which Materials should be shipped (please be specific):

_____

Company Name & Department

Address:

_____

_____

_____

_____

APPENDIX B – EXAMPLE ROYALTY REPORT

Required royalty report information includes:

? OTT license reference number (L-XXX-200X/0)
? Reporting period
? Catalog number and units sold of each Licensed Product (domestic and foreign)
? Gross Sales per catalog number per country
? Total Gross Sales
? Itemized deductions from Gross Sales
? Total Net Sales
? Earned Royalty Rate and associated calculations
? Gross Earned Royalty
? Adjustments for Minimum Annual Royalty (MAR) and other creditable payments made
? Net Earned Royalty due

Example

Catalog Number	Product Name	Country	Units Sold	Gross Sales (US$)
1	A	US	250	62,500
1	A	UK	32	16,500
1	A	France	25	15,625
2	B	US	0	0
3	C	US	57	57,125
4	D	US	12	1,500

Total Gross Sales	153,250
Less Deductions:	
Freight	3,000
Returns	7,000
Total Net Sales	143,250
Royalty Rate	8%
Royalty Due	11,460
Less Creditable Payments	10,000
Net Royalty Due	**1,460**

APPENDIX C – ROYALTY PAYMENT OPTIONS

NIH/PHS License Agreements

****In order to process payment via Electronic Funds Transfer sender MUST supply the following information:***

Procedure for Transfer of Electronic Funds to NIH for Royalty Payments

Bank Name: Federal Reserve Bank

ABA# 021030004
TREAS NYC
BNF=/AC-75080099
OBI=Licensee Name and OTT Reference Number
Dollar Amount Wired=$$

NOTE: Only U.S. banks can wire directly to the Federal Reserve Bank. Foreign banks cannot wire directly to the Federal Reserve Bank, but must go through an intermediary U.S. bank. Foreign banks may send the wire transfer to the U.S. bank of their choice, who, in turn forwards the wire transfer to the Federal Reserve Bank.

Mailing Address for Royalty Payments:

National Institutes of Health
P.O. Box 360120
Pittsburgh, PA 15251-6120 USA

Overnight Mail for Royalty Payments only

National Institutes of Health
360120
Mellon Client Service Center
Room 670
500 Ross Street
Pittsburgh, PA 15262-0001

(301) 496-7735 extension 214

Please make checks payable to: *NIH/Patent Licensing*

*The OTT Reference Number **MUSY** appear on checks, reports and correspondence*